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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,681	06/27/2003	David Wynn	MCP-5016 NP	8293
27777	7590	10/16/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			STITZEL, DAVID PAUL	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 10/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/608,681	WYNN ET AL.	
	Examiner	Art Unit	
	David P. Stitzel, Esq.	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-17 is/are rejected.
- 7) ☒ Claim(s) 9 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/26/06; 10/14/04</u> . | 6) <input type="checkbox"/> Other: _____ |

OFFICIAL ACTION

Acknowledgment of Receipt

Receipt of the Applicants' Election, *with traverse*, of: 1. ibuprofen as the patentably distinct species of pharmaceutically active ingredient; 2. hydroxypropylmethylcellulose as the patentably distinct species of hydroxyalkylcellulose; and 3. mannitol as the patentably distinct species of carbohydrate; which was filed on July 31, 2006, in response to the Official Action dated June 29, 2006, is acknowledged.

Applicant's traversal of the aforementioned species election requirement on the grounds that said requirement is improper and that a prior art search and examination of the claims of the inventions as originally presented would not impose a serious search burden, is duly noted. However, a proper *prima facie* case of undue search burden associated with a prior art search and examination of the claims of the patentably distinct species has previously been established in the aforementioned Official Action. If Applicants are of the opinion that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is in fact the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other inventions. As a result, the species election requirement is deemed proper and therefore made FINAL.

Status of Claims

Claim 6 is withdrawn from further consideration as being directed to a non-elected invention. As a result, claims 1-5 and 7-17 are therefore examined herein on the merits for patentability.

Remark Regarding Provisional Nonstatutory Double Patenting

1. A provisional nonstatutory double patenting rejection is not being made over copending U.S. Patent Application, Serial Number 10/607,766 (hereinafter the copending Wynn '766 application) because although the elected pharmaceutically active ingredient, namely ibuprofen, in the instant application is identical to the elected pharmaceutically active ingredient in the copending Wynn '766 application, the elected hydroxyalkylcellulose, namely hydroxypropylmethylcellulose, in the instant application is patentably distinct from the elected hydroxyalkylcellulose, namely hydroxypropylmethylcellulose phthalate, in the copending Wynn '766 application. Moreover, unlike the composition of the instant application, the composition of the copending Wynn '766 application requires an insoluble film forming polymer, namely cellulose acetate. Therefore, because the instantly claimed composition of the instant application is patentably distinct from, and not an obvious variation of, the composition presently claimed in the copending Wynn '766 application, a provisional nonstatutory double patenting rejection is not currently being made.

Claim Objections

1. Claims 9 and 16 are objected to because of the following informalities: "hydroxypropylcellulose *and/or* hydroxypropylmethylcellulose" is improper Markush language. Correction utilizing appropriate Markush language (i.e., "wherein said hydroxyalkylcellulose is selected from the group consisting of: hydroxypropylcellulose; hydroxypropylmethylcellulose; and mixtures thereof") is required. See MPEP § 2173.05(h).

Claim Rejections - 35 U.S.C. § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112, which forms the basis of the claim rejections as set forth under this particular section of the Official Action:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 14-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. With respect to claim 14, confusion exists as to what constitutes “substantially free” of hydroxypropylmethylcellulose? More specifically, the phrase “substantially free” is a relative term that renders claim 14 indefinite. The phrase “substantially free” is not defined within said claim, the instant specification does not appear to provide a standard for ascertaining the requisite degree of what constitutes “substantially free” of hydroxypropylmethylcellulose, and one of ordinary skill in the art would not be reasonably apprised of the scope of the claimed invention. In addition, the wherein phrase of claim 14 seems to exclude the presence of hydroxypropylmethylcellulose, even though hydroxypropylmethylcellulose is a claimed ingredient and thus limitation, which must be present within the composition as instantly claimed. Claims 15-17, which are dependent upon and include all of the limitations of independent claim 14, are therefore likewise rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Appropriate correction is required.

2. Claims 1-5 and 7-17 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. With respect to independent claims 1 and 14, confusion exists as whether the claim

language reciting “hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 *and/or* a viscosity of from about 3,000 mPa · s to about 150,000 mPa · s in a 2% aqueous solution,” is intended to mean that a hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 likewise possesses a viscosity of from about 3,000 mPa · s to about 150,000 mPa · s in a 2% aqueous solution, and *vice versa*, or whether a hydroxyalkylcellulose having a weight average molecular weight of from about 60,000 to about 5,000,000 need not necessarily possess a viscosity of from about 3,000 mPa · s to about 150,000 mPa · s in a 2% aqueous solution, and *vice versa*? Therefore, the phrase “and/or” renders said claims indefinite because the meets and bounds of said claims is unclear, as confusion exists with respect to the intended scope of said claims. See MPEP § 2173.05(d). Claims 2-5 and 7-13, which are dependent upon and include all of the limitations of independent claim 1, and claims 15-17, which are dependent upon and include all of the limitations of independent claim 14, are therefore likewise rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Appropriate correction is required.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of the appropriate paragraph of 35 U.S.C. § 103, which forms the basis of the obviousness rejections as set forth under this particular section of the Official Action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-5 and 7-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent 4,835,187 (hereinafter the Reuter '187 patent) in view of Lachman L, Lieberman HA, Kanig JL, *The Theory and Practice of Industrial Pharmacy*, Lea &Febiger Publishing, pp. 315-317 (1986) (hereinafter the Lachman publication).

With respect to claims 1-5 and 7-17 of the instant application, the Reuter '187 patent teaches an immediate release composition in chewable solid dosage form comprising: a plurality of inert silica particles of about 10 millimicrons (i.e., 10 nm or 0.01 μm) comprising ibuprofen, which is present in an amount of from about 40 wt. % to about 70 wt. %; USP hydroxypropylmethylcellulose grades E, F and K (e.g., Methocel/HPMC E4MP) having a viscosity ranging from about 3,500 centipoise to about 5,600 centipoise (i.e., from about 3,500 mPa · s to about 5,600 mPa · s) and present in an amount ranging from 15 wt. % to about 50 wt. %; and mannitol (abstract; column 1, lines 1-68; column 2, lines 1-68; column 3, lines 6-68; column 4, lines 6, 22 and 56-68; column 5, lines 1-9).

With respect to claims 1 and 14 of the instant application, although the Reuter '187 patent teaches a plurality of inert silica particles comprising ibuprofen and having particle diameters of about 10 millimicrons (i.e., 10 nm or 0.01 μm), the Reuter '187 patent does not explicitly teach that said

plurality of inert silica particles comprising ibuprofen have particle diameters ranging from about 150 μm to about 400 μm as instantly claimed. However, while the Reuter '187 patent does not explicitly teach the instantly claimed particle diameters ranging from about 150 μm to about 400 μm , it is well within the purview of the skilled artisan to determine the optimal diameter of said particles by systematically adjusting the diameters thereof during the course of routine experimentation. One of ordinary skill in the art at the time the instant application was filed would have been motivated to systematically adjust the diameters of said particles during the course of routine experimentation so as to obtain a free-flowing composition exhibiting desired flow properties that are suitable for manufacturing processing, as reasonably suggested by the Lachman publication (page 315, column 2, lines 6-24; page 316, column 2, lines 51-58; page 316, column 1, lines 1-23). One of ordinary skill in the art at the time the instant application was filed would have been motivated to increase the particle diameters of the Reuter '187 patent so as to avoid excessive van der Waals attractive forces that exist among particles having particle diameters of less than or equal to 150 μm , which result in a composition exhibiting undesirable flow properties, such as clumping, and thus undesirable manufacturing processing characteristics, as reasonably suggested by the Lachman publication (page 315, column 2, lines 6-24; page 316, column 2, lines 51-58; page 316, column 1, lines 1-23). "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." See *In re Aller*, 105 USPQ 233, 235 (CCPA 1955). "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages." See *Peterson*, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

With respect to claims 1, 2 and 14 of the instant application, although the Reuter '187 patent teaches a composition comprising USP hydroxypropylmethylcellulose grades E and K (e.g.,

Methocel/HPMC E4MP) having a viscosity ranging from about 3,500 centipoise to about 5,600 centipoise (i.e., from about 3,500 mPa · s to about 5,600 mPa · s), the Reuter '187 patent does not explicitly teach that said USP hydroxypropylmethylcellulose grades E and K (e.g., Methocel/HPMC E4MP) have an average molecular weight of from about 60,000 to about 5,000,000, and more particularly from about 140,000 to about 1,150,000, as instantly claimed. However, the instant specification states that HPMC K4M is a particularly suitable hydroxypropylmethylcellulose. See [0019] and [0054] of U.S. Pre-Grant Patent Application Publication 2004/0265373, which is the published version of the instant application. Examples of USP hydroxypropylmethylcellulose grades E and K having a viscosity ranging from about 3,500 centipoise to about 5,600 centipoise (i.e., from about 3,500 mPa · s to about 5,600 mPa · s), as disclosed in the Reuter '187 patent, include not only Methocel/HPMC E4MP, which has a viscosity of from about 2,308 mPa · s to about 3,755 mPa · s, but also Methocel/HPMC K4M, which has a viscosity of from about 2,308 mPa · s to about 3,755 mPa · s. Therefore, both Methocel/HPMC K4M and E4MP must also possess an average molecular weight ranging from about 60,000 to about 5,000,000, and more particularly ranging from about 140,000 to about 1,150,000, as instantly claimed.

With respect to claim 7 of the instant application, although the Reuter '187 patent teaches a composition comprising ibuprofen, which is present in an amount of from about 40 wt. % to about 70 wt. %, and USP hydroxypropylmethylcellulose grades E, F and K (e.g., Methocel/HPMC E4MP), which is present in an amount ranging from 15 wt. % to about 50 wt. %, the Reuter '187 patent does not explicitly teach hydroxypropylmethylcellulose being present in an amount of from about 0.5 wt. % to about 10 wt. %, as instantly claimed. However, the instant specification states that ibuprofen is only present in an amount of from about 0.1 wt. % to about 25.0 wt. %, which is dramatically less than the amount of ibuprofen disclosed in the Reuter '187 patent. It would have been prima facie obvious to

one of ordinary skill in the art at the time the instant application was filed to decrease the amount of the taste neutralizing hydroxypropylmethylcellulose present within the composition disclosed in the Reuter '187 patent, in the event that a lower amount of unpalatable ibuprofen is incorporated into the composition of the Reuter '187 patent. One of ordinary skill in the art at the time the instant application was filed would have been motivated to decrease the amount of the taste neutralizing hydroxypropylmethylcellulose when a lower amount of unpalatable ibuprofen is incorporated into the composition of the Reuter '187 patent, so as to achieve the same desired taste neutralizing characteristic of said composition without the unjustifiable expense of incorporating additional unnecessary hydroxypropylmethylcellulose.

In regard to claim 11 of the instant application, "[e]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985).

With respect to claim 13 of the instant application, although the Reuter '187 patent does not explicitly teach that said composition has a moisture content of not more than about 5 wt. %, the Reuter '187 patent explicitly teaches that said composition undergoes drying within a dryer having an inlet temperature of from about 153°C to about 210°C, and an outlet temperature of from about 94°C to about 108°C, which would intrinsically render said composition of the Reuter '187 patent having a moisture content of not more than about 5 wt. %, as instantly claimed.

Conclusion

Claims 1-5 and 7-17 are rejected because the claimed invention would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made since each and every element of the claimed invention, as a whole, would have been reasonably suggested by the teachings of the cited prior art references.

Remarks

The following are electronic non-patent literature made of record and considered pertinent to the Applicant's disclosure, but are not however currently relied upon in construing the claim rejections as set forth herein:

- <http://www.dow.com/dowexcipients/products/methocel.htm>;
- http://www.colorcon.com/pharma/mod_rel/methocel/literature/methocel_k4m.pdf; and
- http://www.colorcon.com/pharma/mod_rel/methocel/literature/methocel_e4m.pdf.

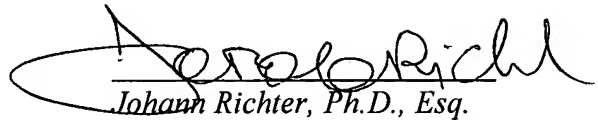
Contact Information

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to David P. Stitzel, M.S., Esq., whose telephone number is 571-272-8508. The Examiner can normally be reached on Monday-Friday, from 7:30AM-6:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Johann Richter, Ph.D., Esq., can be reached at 571-272-0646. The central fax number for the USPTO is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published patent applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished patent applications is only available through Private PAIR. For more information about the PAIR system, please see <http://pair-direct.uspto.gov>. Should you have questions about acquiring access to the Private PAIR system, please contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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